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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,480	03/06/2000	BRIGITTE GICQUEL	0660-0165-0X	5139

7590 04/03/2002

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 04/03/2002

(8)

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/462,480	GICQUEL ET AL.
	Examiner	Art Unit
	Rodney P. Swartz, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 56-70 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 56-70 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 11January2002, paper#16, is acknowledged.

Claims 1-55 have been canceled with prejudice.

New claim 56-70 have been added. However, it is noted that two identical claim 60 appear in applicants' response, i.e., once at the bottom of page 5 and again at the top of page 6. Therefore, the duplicate claim 60 at the top of page 6 has not been entered.

2. Claims 56-70 are pending and under consideration.

### **Drawings**

3. The formal drawings received 11January2002, paper#17, have been reviewed by the Draftsperson and approved.

### **Rejection Withdrawn**

4. The rejection of claims 16-24, 26-29, 31, and 33 under 35 U.S.C. §112, second paragraph, indefiniteness for dependence from a nonelected claim, is moot in light of the cancelation of the claims.

5. The rejection of claims 21 and 22 under 35 U.S.C. §112, second paragraph, lack of antecedent basis, is moot in light of the cancelation of the claims.

6. The rejection of claims 21 and 22 under 35 U.S.C. §112, second paragraph, indefiniteness for "portions of the polypeptide of SEQ ID NO:4", is moot in light of the cancelation of the claims.

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7. The rejection of claim 23 under 35 U.S.C. §112, second paragraph, indefiniteness for “MAP” and “under the form of”, is moot in light of the cancelation of the claim.
8. The rejection of claim 23 under 35 U.S.C. §112, second paragraph, indefiniteness for “additional T-epitope”, is moot in light of the cancelation of the claim.
9. The rejection of claims 23, 24, 26-29, 31, and 33 under 35 U.S.C. §112, second paragraph, indefiniteness for lack of antecedent basis, is moot in light of the cancelation of the claims.
10. The rejection of claims 27-29 under 35 U.S.C. §112, first paragraph, scope of enablement for “vaccines”, is moot in light of the cancelation of the claims.
11. The rejection of claim 31 under 35 U.S.C. §112, second paragraph, incomplete for omitting essential steps, is moot in light of the cancelation of the claim.
12. The rejection of claim 31 under 35 U.S.C. §112, second paragraph, indefiniteness for detection of whole bacterium, is moot in light of the cancelation of the claim.

#### **Rejections Maintained**

13. The rejection of claims prior 16, 23, 24, 26-29, 31 and 33, now rewritten as new claims 56-70 under 35 U.S.C. §112, second paragraph, indefiniteness for polypeptide expressed by a host “containing” specific polynucleotides, is maintained.

The newly rewritten claims, dependent from claims 56 and 57, remain drawn to a purified polypeptide expressed by a recombinant host which contains a polynucleotide selected from

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polynucleotides “comprising” various specific polynucleotides. The open language of the new claims does not correct indefiniteness of the prior rejected claims.

Claim 57 is drawn to a purified polypeptide comprising at least one antigenic portion of a polypeptide comprising SEQ ID NO:5 or specific portions of SEQ ID NO:5. However, because of the open language “comprising”, the antigenic portion is not restricted to SEQ ID NO:5 but may also originate in the nondefined regions of the polypeptide.

**14.** The rejection of claims prior 31 and 33, now rewritten as new claims 69 and 70 under 35 U.S.C. §112, first paragraph, scope of enablement, for antibody assays or other proteins is maintained for reasons of record.

The newly rewritten claims remain drawn to a method and kit comprising a polypeptide of claim 56 (see maintained rejection immediately above). The identity of said polypeptide is not restricted to the specific SEQ ID Nos nor even to *Mycobacterial* origin. In addition, the specification to which applicants’ response is directed teaches only DTH responses, not antibody responses.

### **Conclusion**

**15.** No claims are allowed.

**16. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

April 1, 2002